

## REMARKS

Claims 1-7 and 19 are currently pending. Claims 1-7 are allowed. Claims 8-18, withdrawn pursuant to a restriction requirement, are cancelled, without prejudice to the prosecution of their subject matter in other patent applications. Claim 19 is amended herein, and none of the amendments to claim 19 constitute new matter.

Claim 19 is rejected under 35 U.S.C., second paragraph as being indefinite and under §112, first paragraph as failing to comply with the written description and enablement requirements. Claim 19 is also rejected under 35 U.S.C. §102(a) and §102(b) as being anticipated by prior art references.

For reasons detailed below, the rejections should be withdrawn and claims allowed to issue. Entry of the foregoing amendments is respectfully requested.

### **1. Claim 19 As Amended Is Definite**

Claim 19 is rejected under 35 U.S.C. §112, second paragraph, as indefinite for reciting “a panel of control B lymphocytes”, because, according to the Examiner, “one does not know what factors/variables these “control” for in the methods.”

Applicant has amended claim 19 to more particularly claim the subject matter of the invention, by referring to “panels of separated B- and T- lymphocytes from control individuals representative of the most frequently encountered HLA class I and class II antigens,” wherein the control aspect lies in the representation of the most frequently encountered HLA class I and class II antigens. In view of this amendment, it is requested that the rejection be removed.

### **2. Claim 19 Complies With The Written Description Requirement**

Claim 19 is rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement because, according to the Examiner:

Claim 19 contains new matter because recitation of merely “a panel of control B lymphocytes” is overly broad in comparison to “B-lymphocytes obtained from a panel of control individuals representative of the most frequently encountered HLA class I and class II antigen in the general population.”

Claim 19 is amended to refer to “panels of separated B- and T- lymphocytes from control individuals representative of the most frequently encountered HLA class I and class II antigens,” thereby obviating the basis for the rejection, which should be removed.

**3. Claim 19 Is Enabled**

Claim 19 is rejected under 35 U.S.C. §112, first paragraph, as unenabled, because, according to the Examiner, “it appears that two control panels of B- and T-lymphocytes are needed and that one determines DR (class II) reactivity by virtue of obtaining a ratio of reactivity against B-versus T-lymphocytes.”

Claim 19 is amended to refer to panels of B-and T-lymphocytes and to require determination of a ratio, thereby obviating the basis of the rejection, which should be removed.

**4. Claim 19 Is Not Anticipated**

Claim 19 is rejected under 35 U.S.C. §102(a) and §102 (b) as being anticipated by Itescu et al. (Circulation 1998, 98: 786) and Itescu et al. (J Heart Lung Transplant. 1997, 16: 78) respectively. The Examiner states:

The examiner does not consider that mere recitation of “post transplant” in claim 19 overcomes, because in each of the references 23 of the patients may be reasonably considered as “post-transplant” recipients; this is because these 23 patients “were recipients of a second cardiac allograft.” . . . Thus, while the analysis presented by Itescu et al. can be considered [*pre-transplant*] with respect to all of the patients (45 who had received a “first” transplant), the analysis may also be considered as “post-transplant” for those 23 patients who had been previously transplanted. To overcome applicant must recite claim 19 with more precise language, so that it is clear that “detection of IgG anti-HLA-DR antibodies occurs “post-transplant” with respect to the particular tissue allograft that the “recipient is likely to reject” and not with respect to some other tissue allograft that the recipient has previously rejected.

To expedite the allowance of claim 19, Applicant has followed the suggestion of the Examiner and has amended claim 19 to specify that the method relates to “a subject who *has received* a tissue allograft” and predicting whether the subject “is likely to reject *the* tissue allograft” thereby establishing, through verb tense and antecedence the sequence of events (transplant placement followed by testing) and the fact that the allograft that was placed in the recipient is the same graft for which the likelihood of rejection is being tested. In view of the

differences between the teachings of cited references by Itescu et al., and the subject matter encompassed by claim 19 as amended, the rejections under 35 U.S.C. §102(a) and §102(b), should be withdrawn and all the claims be allowed to issue.

**5. Conclusion**

Entry of the foregoing amendments and remarks into the file of the above-identified application is respectfully requested. The Applicant believes that the invention described and defined by amended claim 19 is patentable over the rejections of the Examiner. Withdrawal of all rejections and reconsideration of the amended claim is requested. An early allowance is earnestly sought.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Lisa B. Kole", is written over a horizontal line.

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